K012543

JUL 15 2002

510(k) Summary

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Vision-Sciences, Inc. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." VSI chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Trade Name: **EndoSheath® System for use with ENT Scopes**

Owner/Operator: Vision-Sciences, Inc.
9 Strathmore Rd.
Natick, MA 01760

Manufacturing Site: Vision-Sciences, Inc.
9 Strathmore Rd.
Natick, MA 01760
Reg. # 1223490

Device Generic Name: Nasopharyngo-laryngoscope and accessories

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards 21 CFR 874.4760; 77EOB.

Predicate Devices: **EndoSheath® System for use with ENT Scopes (K990354)**
Manufactured and distributed by:
Vision-Sciences, Inc.
9 Strathmore Rd.
Natick, MA 01760

Thermometer Covers
Marketed by:
Becton Dickinson, Stop & Shop

Transesophageal Ultrasound Probe Covers
Marketed by:
Hewlett Packard

Product Description:
The VSI ENT EndoSheath® System consists of a sterile, disposable, protective sheath which covers the patient contact portion of the scope during a clinical procedure. The sheath is removed and disposed of following each procedure. This 510(k) addresses modifications to the EndoSheath® System Instruction Manual.

Indications for Use:
The Vision Sciences EndoSheath® Systems are indicated for use as a protective covering for the scope during endoscopic examination of the upper airway, vocal chords and/or nasal passages.

Conclusion:
Based on the indications for use, technological characteristics, and comparison to predicate devices, the EndoSheath® Systems for use with Flexible ENT scopes have been shown to be safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2002

Vision Sciences, Inc.
c/o Pam Papineau, RAC
Delphi Medical Device Consulting
5 Whitcomb Avenue
Ayer, MA 01432

Re: K012543
Trade/Device Name: Endosheath System
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: June 21, 2002
Received: June 26, 2002

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address. http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): 01 2543

Device Name: EndoSheath® System for use with Flexible ENT Scopes

Indications for Use:

The EndoSheath® System provides a sterile, disposable protective covering for the scope to be used during flexible endoscopic examination of the upper airway, vocal chords and/or nasal passages.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)

...n Sign-Off)
...ion of Ophthalmic Ear,
... and Throat D vises

Number K01 2543